DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0924]

Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry.'' This guidance is intended to provide recommendations for information that is to be included in premarket submissions—investigational device exemption (IDE), premarket approval application (PMA), and 510(k) submisions for medical devices that either contain or are exposed to animal-derived materials during manufacturing.

DATES: Written comments concerning this guidance must be received by (*insert date 90 days after date of publication in the* **Federal Register**). Comments submitted after (*insert date 90 days after date of publication in the* **Federal Register**), must be submitted to one of the contact persons.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this guidance must be submitted to the Dockets Management Branch (HFA–

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Karen F. Warburton, Office of Device Evaluation (HFZ–460), or Kiki B. Hellman, Office of Science and Technology (HFZ–113), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–7158.

SUPPLEMENTARY INFORMATION:

I. Background

FDA believes that an animal disease such as bovine spongiform encephalopathy (BSE) is a concern in the manufacture of FDA-regulated products intended for administration to humans. In 1993 and, more recently, on May 6, 1996, FDA issued letters to manufacturers to request that bovine-derived materials from cattle which have resided in or originated from countries where BSE has been diagnosed (as designated by the U.S. Department of Agriculture) not be used in the manufacture of FDA-regulated products. To identify medical devices which either contain or are exposed to animal-derived materials during manufacturing, CDRH developed the biomaterials database that contains an inventory of these devices, including type of material, animal species and county of origin, and target organ or tissue for each device. Originally proposed in response to the BSE issue, the database was expanded to include all animal-derived products (including human) in order to respond to other animal-based sourcing concerns that may arise in the future.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical devices containing materials derived from animal sources. It does not create or confer any rights for or

on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's) which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's. The agency is accepting public comments, but it is implementing this guidance immediately because of public health concerns related to the use of bovine-derived materials in medical devices and the agency's previous communication to manufacturers on this subject.

III. Electronic Access

In order to receive ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry'' via your fax machine, call the CDRH Facts–On–Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (2206) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Medical Devices Containing Materials Derived From Animal Sources (Except In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Medical Devices Containing Materials Derived From Animal

Sources (Except for In Vitro Diagnostic Devices). Guidance for FDA Reviewers and Industry" will be available at http://www.fda.gov/cdrh/ode/guid.html.

IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to Dockets Management Branch (address above) written comments regarding this immediately in effect guidance. At any time after 90 days from the date of publication in the **Federal Register**, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit

one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10-28-98
October 28, 1998

D.B. Burlington
Director
Center for Devices and Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

BILLING CODE 4160–01–F